

The conclusion of draft 4, written by Dr. Gallo, acknowledges the source of LAV, notes that LAV grew in H4⁷⁴ and produced cytopathic effects similar to those of HTLV-III. The conclusion then notes that the perceived differences between LAV and HTLV-III may be "due to insufficient characterization of the isolate due to poor virus production." The title page of this version reflects Dr. Gallo's handwritten note "way to deal this LAV originally."⁷⁵

Versions 5 and 6 are substantially the same as version 4 and conclude, through Dr. Gallo's hand, that "the establishment of T-cell populations described here, which continuously grow and produce virus after infection has opened the way to routinely detect the highly cytopathic variants of HTLV in AIDS and provides the first opportunity for the detailed molecular and immunological analysis and for the resolution of relatedness of HTLV-III and LAV." Exhibit H-53 at 9 (Emphasis supplied.) ORI will show this statement is significant for two reasons. First, it suggests that the opportunity for the resolution of the relationship between the isolates had not previously existed because LAV purportedly had not been grown in a permanent cell

⁷⁴ Although LAV did not grow in H4, the isolate labeled MOV did. This statement by Dr. Gallo was changed again in Version 7 in which H4 was changed to HT. Moreover, the fact that Dr. Gallo wrote in the draft that LAV had been grown in H4 puts to rest any debate as to whether Dr. Gallo knew that LAV had been grown in a permanent cell line.

⁷⁵ Dr. Gallo asserts that he does not recall what he meant when he wrote "originally." Transcript of R. Gallo (April 12, 1991) at 12, Exhibit H-316.

line. See also Exhibits H-118, 121, and 130. The statement is false because LAV had been grown in a permanent cell line and Dr. Gallo knew it. Second, the statement is significant because it links the LTCB's work with the HIV-infected cell lines HT and H9 to a determination of the relationship between LAV and HTLV-III. During the OSI investigation, however, Dr. Gallo claimed that the LTCB's work was not directed to determining the HTLV/LAV relationship. See Dr. Gallo's Response to ORI Final Report at 2 (Nov. 9, 1992).

By draft 8, the same draft in which the reference to the LTCB's growth of LAV was finally deleted, the reference to "resolution of the relatedness of HTLV-III and LAV" was also deleted. Draft 7 is substantially the same as draft 6 but the reference to H4 is changed to HT. Compare Exhibits H-53 and H-54.

In draft 8, the references to LAV's being a gift from Drs. Montagnier and Chermann of the Pasteur as well as the acknowledgement that LAV was grown in HT and has similar cytopathic effects are deleted. The sentence referring to LAV's characterization is modified to read, "however, it is possible that this is due to insufficient characterization because of poor virus production." Furthermore, the final sentence is truncated to eliminate the clause "and for the resolution of HTLV-III and LAV."

8. Dr. Gallo's Explanations are Not Credible

ORI will prove that the progression of changes Dr. Gallo made to the Popovic paper demonstrates a continuation of his efforts to obscure the use and significance of LAV in the LTCB's research. Dr. Gallo's efforts culminated in his false and misleading statements in the Science paper that LAV had been insufficiently characterized, not transmitted to a permanent cell line and difficult to obtain in quantity. See also Exhibits H-83-84. ORI will show that Dr. Gallo's actions amount to scientific misconduct.

Dr. Gallo's efforts to obfuscate the truth will be further demonstrated by a review of Dr. Gallo's varying explanations for the false statements, explanations he apparently jettisoned by settling upon the explanation du jour that he was referencing the French peer reviewed published literature.⁷⁶ ORI will demonstrate that Dr. Gallo's explanation that the LAV statement in the Science paper is limited to the accomplishments of the French as published in the peer-reviewed literature are not credible. Indeed, ORI will show that this carefully crafted sentence simply is not written to convey this meaning.

⁷⁶ Dr. Gallo explained that he did not reveal that his laboratory had grown LAV in a permanent cell line because (1) he did not believe that he had the authority to publish information on LAV; (2) it would have embarrassed the French because they repeatedly had stated that LAV could not be grown in a permanent cell line (Transcript of R. Gallo (Dec. 2, 1990) at 66); (3) he would have had to include data on LAV and make the French co-authors (Id. at 66); and (4) he believed that his laboratory had grown LAV in a permanent cell line only transiently which was irrelevant to the subject of the Popovic paper. (Id. at 184).

Rather, it is a sentence written as if it were generally true that LAV had not been grown in a permanent cell line. Nothing in the structure of the LAV sentence and the statements that precede it give an indication that the statement was intended to refer only to the published work of the French. Indeed, nowhere is this intent disclosed or even suggested. Rather, the first half of the challenged sentence clearly says, "[h]owever, it is possible that this is due to insufficient characterization of LAV because the virus has not been transmitted to a permanently growing cell line...." (Emphasis supplied). ORI will demonstrate that the use of the word "this" is significant. "This" clearly refers to the suggestion in the preceding sentence that "HTLV-III and LAV may be different." Dr. Gallo's suggestion that HTLV-III and LAV may be different is a general observation about HTLV-III and LAV, and is nowhere limited to the Pasteur's published peer reviewed literature. Moreover, the suggestion is the predicate for the equally general statements that follow: 1) there has been insufficient characterization of LAV, 2) LAV has not been transmitted to a permanently growing cell line, and 3) LAV has been difficult to obtain in quantity. (See also Exhibit H-81 at 501, which makes similar general observations about LAV: "This isolate has been difficult to grow in quantities sufficient to permit its characterization.")

In short, none of the observations relating to LAV in the Science paper was specified by Dr. Gallo to be limited to the

work of the Pasteur scientists; all appear in the paper to be general observations about the isolate.

Although portions of the discussion incorporating the disputed passage appropriately cite Pasteur papers, the discussion also cites both papers published by non-Pasteur laboratories and numerous conclusions drawn from unpublished work.⁷⁷ Clearly, the disputed statement does not offer an analysis of the Pasteur accomplishments; it purports to explain the alleged apparent differences between LAV and HTLV III.

Drs. Gallo and Popovic could have cited the French Science May 1983 paper for the proposition that the French had not grown --- or not reported growing --- LAV in a permanent cell line had they so intended, but they did not. Moreover, ORI will show that, when Dr. Popovic was asked for his own interpretation of the statement, i.e., that it applies exclusively to the French published literature, Dr. Popovic reiterated his opinion that his LAV data should have been included (Transcript of M. Popovic (Dec. 1, 1990), Exhibits H-320; 121; 140, pp. 155-56) Dr. Gallo's post hoc explanation is further significantly undercut by the fact that prior drafts of the section written by Dr. Gallo

⁷⁷ Other papers cited in the paragraph include the other Science papers accompanying the Popovic paper. The French papers are cited only twice. Unpublished findings include findings that (1) LAV is unrelated to HTLV-I (Montagnier et al.; Cold Spring Harbor, in press); (2) 37.5% of AIDS patients' sera react with LAV (Montagnier et al.; Cold Spring Harbor in press is cited, albeit incorrectly: the 37.5% does not appear in the Cold Spring Harbor chapter); (3) HTLV III is related to HTLV I and II (Schupbach et al. Science paper and Arya et al., in preparation).

show that the LAV discussion was focused neither on the accomplishments of the French nor the published literature. Instead, the paper announced that the establishment of LAV in a permanent cell line heralded the way for a definitive comparison of HTLV-III and LAV. Clearly these earlier drafts did not limit their LAV discussions to the published work of the French.

Accordingly, ORI will demonstrate that the message Dr. Gallo conveyed by the challenged statement was that (a) the cited findings represent all the significant scientific information available bearing on the similarity or dissimilarity of LAV and HTLV-III; (b) there has not been a sufficient characterization of LAV by anyone and, consequently, the cited findings may not be conclusive; and (c) the reason there has not been a sufficient characterization of LAV is that LAV has not yet been transmitted to a permanent cell line by anyone and LAV has been difficult to obtain in quantity. See also Exhibits H-67, 169, 171.

Through presentation of the evidence enumerated throughout this offer, ORI will prove that the message sent by Dr. Gallo is false and was known by him to be so. ORI will show:

- the LTCB had performed many studies on LAV; these studies showed that LAV and HTLV-III were at least the same kind of virus, i.e., both were the cause of AIDS; see discussion;
- the LTCB had grown LAV in two permanent cell lines for two-to-three months, yet prior to the OSI investigation Dr. Gallo never revealed that the growth of LAV was continuous. In fact,

he repeatedly stated that LAV had not been grown or had been grown only transiently. See Exhibit H-167; see discussion;

-- Dr. Gallo had knowledge of additional data on LAV, most notably, the AIDS detection rate of the Pasteur blood test in the CDC comparison study, results that showed the IP's LAV-based blood test was as good as or better than Gallo's HTLV-III-based test. Exhibits H-63, 219. Dr. Gallo possessed this knowledge well before the final corrections were made on the galleys to the Popovic paper after the April 23 press conference. Although this CDC and Pasteur data was as yet published so was the 37.5% figure that Dr. Gallo did cite, and thus he cannot successfully claim that he was referenced only published data. Exhibit H-125.

-- Drs. Gallo and Popovic both clearly believed - and said - that LAV and HTLV-III were the same virus type. Indeed, Dr. Popovic even called LAV "HTLV-III" in the first draft of the Popovic paper. Dr. Gallo obfuscated the similarities in this paper. See also Exhibits H-95, 105, 111, 113, 229, 230.

Therefore, ORI will establish that the challenged statement contained in the Science paper asserting that LAV has not been grown in a permanent cell line is false. ORI will further establish that Dr. Gallo knew or should have known that the statement was false and that the statement was material to the messages being conveyed by the paper. Drs. Chermann, Barré-Sinoussi, Martin, Francis, Cabradilla, McGrath, Schaffer and Richards (as well as other members of the Richards Panel) will testify regarding these points. ORI will also show that, in

1984, when the Popovic paper was written, it was a serious deviation from accepted standards in the scientific community and NIH to falsify information in scientific publications and/or deliberately to mislead the scientific community in such published work. Dr. Gallo was aware of the acceptable standards within the community and his actions with respect to the LAV statement amount to scientific misconduct.⁷⁸ Drs. Goldberger, Rall, Morgan, Raub, Huth, Richards (and other members of the Richards Committee), Schaffer and Woolf will testify regarding the acceptable standards in the community and NIH and whether they believe Dr. Gallo violated that standard and whether that violation amounts to scientific misconduct.

Moreover, ORI submits that Dr. Gallo's conduct as evidenced in Allegations A1-A4 and 8 demonstrate a pattern of conduct to "misrepresent, suppress, and distort data and their interpretation in such a way as to enhance his own claims to priority and primacy." Exhibit H-224. This pattern of conduct must be considered in interpreting the standard regarding the growth of LAV contained in the Science paper. When Dr. Gallo's pattern of conduct is taken into account, debate as to Dr. Gallo's intentions underlying the at-issue statement is put to rest. This evidence reveals that Dr. Gallo falsified the at-issue LAV statement and is guilty of scientific misconduct.

ORI WITNESSES

⁷⁸ Exhibit H-223.

Drs. Goldberger, Rall, Morgan, Raub, Huth, Richards (and other members of the Richards Panel), Schaffer, and Woolf will testify regarding the acceptable standards in the community and NIH, what constitutes a serious deviation from those standards and why Dr. Gallo's conduct amounts to scientific misconduct.

Drs. Martin, Cabradilla, Francis, McGrath, Chermann, Montagnier, Barré-Sinoussi, Schaffer, and Hadley will testify about the growth of LAV in the Pasteur and the LTCB and Dr. Gallo's awareness of the growth of LAV in the laboratory.

Drs. Cabradilla, Francis, Murphy, Martin, Chermann, Barré-Sinoussi, Montagnier, Kalyanaraman, Schaffer, and McGrath will testify as to Dr. Gallo's knowledge of the significant characterization of LAV and its availability in large quantities at the time the Science paper was submitted.

Drs. Chermann, Barré-Sinoussi, Martin, Francis, Cabradilla, McGrath, and Schaffer will testify that the statement at issue is both fallacious and clearly misleading.

IV. Applicable Standards of Conduct

For each allegation set forth above, ORI will prove by a preponderance of the evidence:

- A. The applicable standard of scientific conduct in existence at NIH in 1983-84 for a scientist in Dr. Gallo's position;
- B. That Dr. Gallo's conduct seriously deviated from that standard;

C. That such conduct was not due to honest error or honest differences in interpretations of data; and

D. That such conduct constitutes scientific misconduct.

In addition to the various witnesses and documents previously identified, ORI will call the following witnesses to testify on these four issues: Drs. Schaffer, Hadley, McGinnis, Bivens, Goldberger, Huth, Woolf, Francis, and Martin.

V. CONCLUSION

Based on the foregoing, ORI submits this Offer of Proof that Dr. Gallo committed scientific misconduct as described in the following allegations:

A. Allegations A1, A2, A3, A4, and 8 in the aggregate, or any combination thereof that includes allegation 8.

B. Allegation 8 alone. The facts underlying allegations A1-A4 are clearly relevant to, and will be used to prove, a pattern of conduct by Dr. Gallo showing an intent to deceive in allegation 8.

C. Allegation A4 alone. The facts underlying allegations A1-A3 and 8 are clearly relevant to, and will be used to prove, a pattern of conduct by Dr. Gallo showing an intent to deceive in allegation A4.

Respectfully submitted,

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